CBER/OBE/DE

Waiver Request Review Memo

I. Completed by Waiver Coordinator

Product/STN/Reviewer:

Product Name	STN/ NDA	Approval Date	Reviewer
COMIRNATY	125742/8	23-Aug-2021	D. Thompson

CBER Submission Receipt Date: September 15, 2021

Review Memo Action Due Date: October 18, 2021

Type of request:

- ☐ PBRER Waiver Request
- ☐ Request to Change Reporting Period
- ☒ Other: Lot distribution Waiver Request

II. Completed by Medical Officer

Review summary: The sponsor requested a waiver to submit quarterly BLA Lot Distribution Reports (LDR) in lieu of monthly LDR with the justification to align the BLA LDR reporting requirements with the quarterly reporting per the Emergency Use Authorization (EUA) as outlined in the re-authorization issued on August 23, 2021. The Comirnaty BLA approval letter issued on August 23, 2021 requested submission of LDR at monthly intervals.

Note: The sponsor also requested an extension of the first reporting period for the BLA LDR from September 2021 to January 2022 in order to allow for additional time needed to set up required electronic systems needed for submission of the LDR in SPL format and to coincide with the January 2022 EUA report. The request to delay the first reporting period will be granted.

Decision:

- ☐ Waiver granted
- ☒ Waiver declined
- ☐ Request additional information from Licensed Manufacturer

Medical Officer Stamp Date

Deborah L. Thompson -S Digitally signed by Deborah L. Thompson -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002552931, cn=Deborah L. Thompson -S Date: 2021.09.21 18:01:55 -04'00'	9/21/2021

Reference Documents

21 CFR 600.80

Guidance for Industry: Safety Reporting for Human Drug and Biological Products Including Vaccines
https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm092257.pdf

Guidance for Industry: Providing Postmarketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)
https://www.fda.gov/downloads/drugs/guidances/ucm346564.pdf

Guidance for Industry: Providing Submissions in Electronic Format — Postmarketing Safety Reports
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072369.pdf

Guidance for Industry: Addendum to E2C Clinical Safety Data Management: Periodic Safety Update reports for Marketed Drugs, February 2004:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm129444.htm

Guidance for Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report, August 1997:
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071981.pdf

21 CFR 600.81

Electronic Submission of Lot Distribution Reports: Guidance for Industry:
https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM412006.pdf

21 CRF 600.90

http://www.gpo.gov/fdsys/granule/CFR-2011-title21-vol7/CFR-2011-title21-vol7-sec600-90

CFR - Code of Federal Regulations Title 21:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

ICH E2C(R2)- Periodic Benefit-Risk Evaluation Report
http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

CFR - Code of Federal Regulations Title 21:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=600.80